

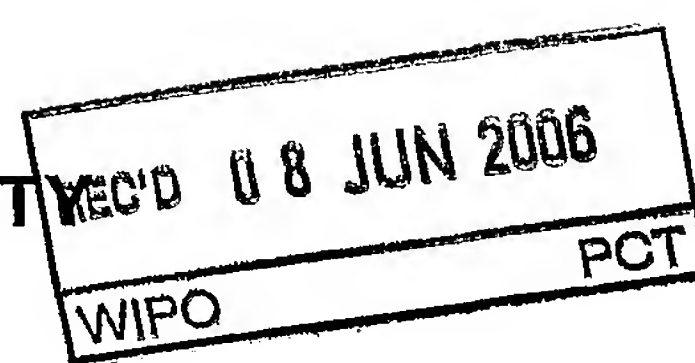
PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 15836 MdH	FOR FURTHER ACTION	See Form PCT/PEA/416
International application No. PCT/GB2005/000645	International filing date (day/month/year) 03.03.2005	Priority date (day/month/year) 13.03.2004
International Patent Classification (IPC) or national classification and IPC INV. C25D11/26 A61F2/30 A61L27/04 A61L27/06 A61L27/30 A61L27/32 A61L27/54 A61L27/56		
Applicant ACCENTUS PLC		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 23.12.2005	Date of completion of this report 08.06.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Espinosa y Carretero Telephone No. +31 70 340-2771 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/000645

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-9 as originally filed

Claims, Numbers

6 as originally filed

1-5 received on 23.12.2005 with letter of 21.12.2005

Drawings, Sheets

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☒ the claims, Nos. 1-5
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/000645

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-6
	No: Claims	
Inventive step (IS)	Yes: Claims	1-6
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-6
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I

The amendments filed with letter dated 21.12.05 introduce subject-matter which extends beyond the content of the application as originally filed, contrary to Article 34(2)(b)PCT. The amendments concerned are the following: "the current density is sufficiently low, the electrolyte concentration sufficiently high".

Re Item V

The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D2 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.

None of the presently available prior art documents disclose the presently claimed subject matter. Thus, the subject matter of Claims 1 to 6 is new (Article 33(2) PCT). The closest prior art in respect of Claim 1 to 6 appears to be document D1 since this document discloses a method of treating a titanium implant by anodising and then performing anion exchange in order to incorporate biocidal metal ions into the surface.

The difference between the method of D1 and the presently claimed method is the present use of a higher voltage in combination with suitable anodisation conditions. Thus, the objective technical problem to be solved is to confer biocidal / hardwearing properties on titanium implants while at the same time retaining the surface properties of the implant surface.

The solution proposed by claim 1 is to control the number and size of the shallow pits by controlling the conditions of the anodisation as described in claim 1.

Even though anodising methods for treating titanium metal implants are known in the art (D1), there is no indication or teaching in document D1 that the particular combination of voltage and duration of treatment disclosed therein would produce the technical effects noted above in contrast to the methods of D1 as shown in Figure 1. Thus the presently claimed subject cannot be obviously derived from the teaching of document D1 and appears to make an inventive contribution to the present art.

Thus, the subject matter of Claim 1 to 6 is inventive (Article 33(3) PCT).

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Claims

1. A method of treating a titanium metal implant for use in a surgical procedure, so as to form a surface layer that is integral with the metal substrate and which incorporates a biocidal material, by anodising the implant to form a surface layer and then performing ion exchange so as to incorporate ions of a biocidal metal into the surface layer, characterised in that the method comprises anodising the implant at a voltage above 50 V for a period of at least 30 minutes, so as to generate the surface layer, wherein the current density is sufficiently low, the electrolyte concentration sufficiently high, and the duration of anodising and the magnitude of the anodising voltage are such that the anodising generates a dense hard surface layer and also shallow pits in the surface layer which are filled with a somewhat softer and more porous material.
2. A method as claimed in claim 1 wherein the biocidal metal is silver.
3. A method as claimed in claim 1 or claim 2 wherein the anodising step uses an electrolyte comprising phosphoric acid.
4. A method as claimed in claim 3 wherein the phosphoric acid is of concentration between 5% and 20% by weight.
5. A method as claimed in claim 3 or claim 4 wherein the electrolyte comprises chloride ions at a concentration no more than 500 ppm.